So, you think you want to do a human research ethics application

The National Statement on Ethical Conduct in Human Research (National Statement) tells us that research is "*widely understood to include at least investigation undertaken to gain knowledge and understanding or to train researchers*" and that human research "*is conducted with or about people, or their data or tissue*."

The first question you must ask yourself is *are you doing **human research**?* Consider the National Statement in thinking about your answer and reflect on the Purpose, scope and limits section.

If your answer is yes – then you should apply for ethics approval.

If you're still not sure, Research Governance and Ethics Coordinators (RGE Coordinators) are available to help. Simply email humanethics@rmit.edu.au.

How long will the process take?

It is the Project Owner's responsibility to allow enough time for the ethical review process. Project applications should be early if there are other relevant deadlines such as grant submissions, start dates for studies, etc. Project applications are reviewed in the order in which they are received.

Factors that may have an impact on the timeframe for review include:

- the completeness and quality of the initial project application
- review category, e.g., negligible versus greater than low risk review
- number of project applications currently under active review by the CHEAN or HREC
- response time by the Project Owner to provide requested information
- potential wait for external documents or letters of permission from related items

We recommend you start your application **three (3) months** in advance of your anticipated start date. This will allow time for all steps in this process including any governance review, discussions and any necessary modifications, and then ethical review. This document will help you submit an application that should meet the requirements of the RMIT Human Research Ethics Procedures. This is especially important for Honours and HDR students with time critical deadlines.

All applications for research ethics review must be made in the RMIT Research Ethics Platform (REP).

REP can be accessed via the ***My Ethics*** tab in the **Researcher Portal** or directly via this link: **https://researchethics.rmit.edu.au/**. REP is part of the RMIT single sign on and you can log in using your RMIT e-number or student ID/RMIT email address and password.

The first time you log into the system an account will automatically be created and your information will auto-populate after an overnight system run.

Your Work Area

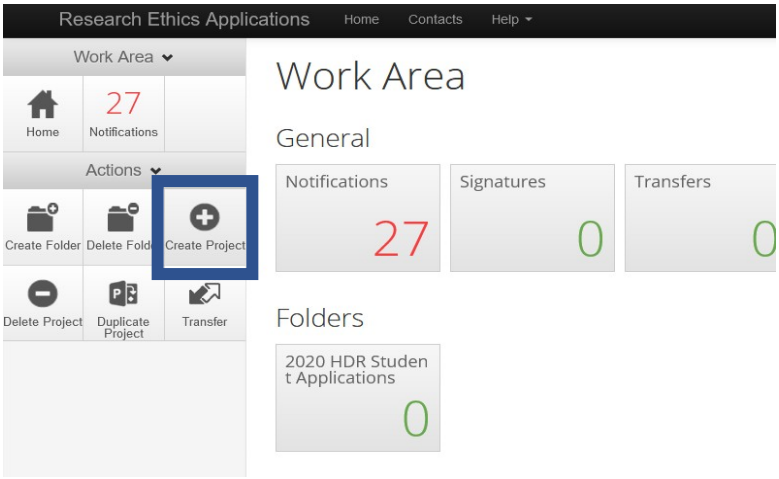
When you log into REP, the page you see first is called the Work Area. This provides an overview

of your projects. You will be able to see where they are in the ethics timeline through REP.

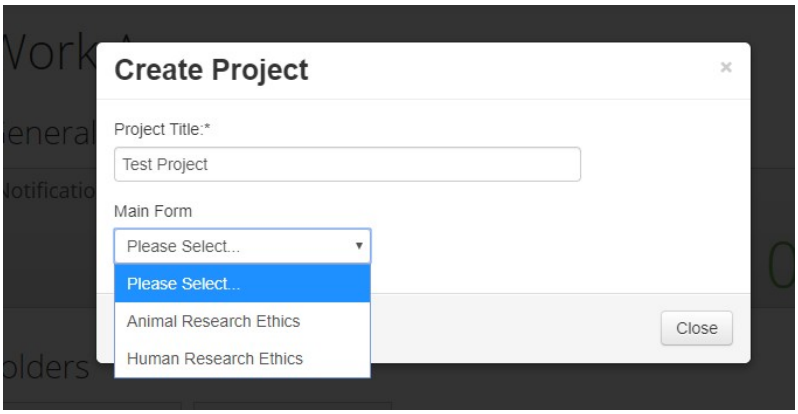
Creating a new Project

A project starts with the main application form and will grow to include its related sub-forms (annual report, final report, adverse events, and amendment requests).

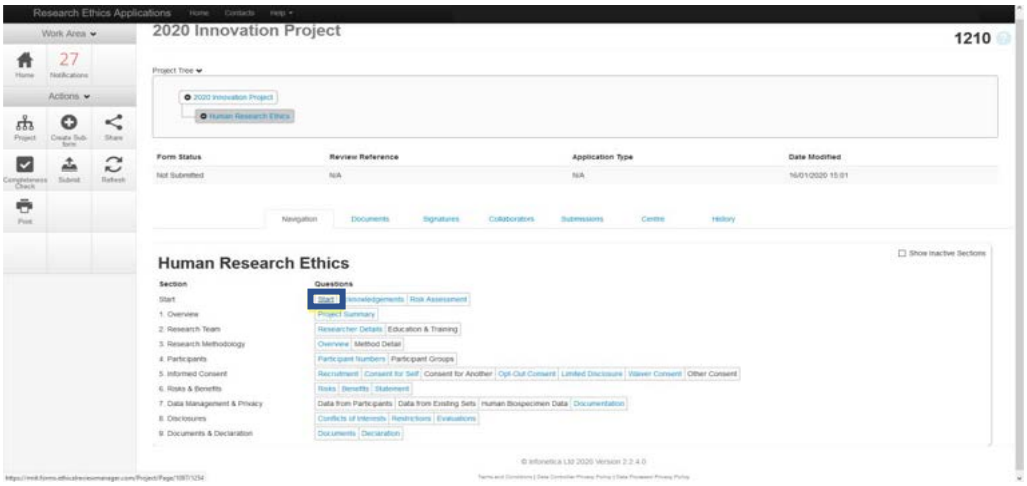
Step 1. On the Actions Panel, click Create Project



Step 2. Enter the project title and select the relevant form from the dropdown list and click Create.



Step 3. You are now in the application form. To begin, click the Start section.



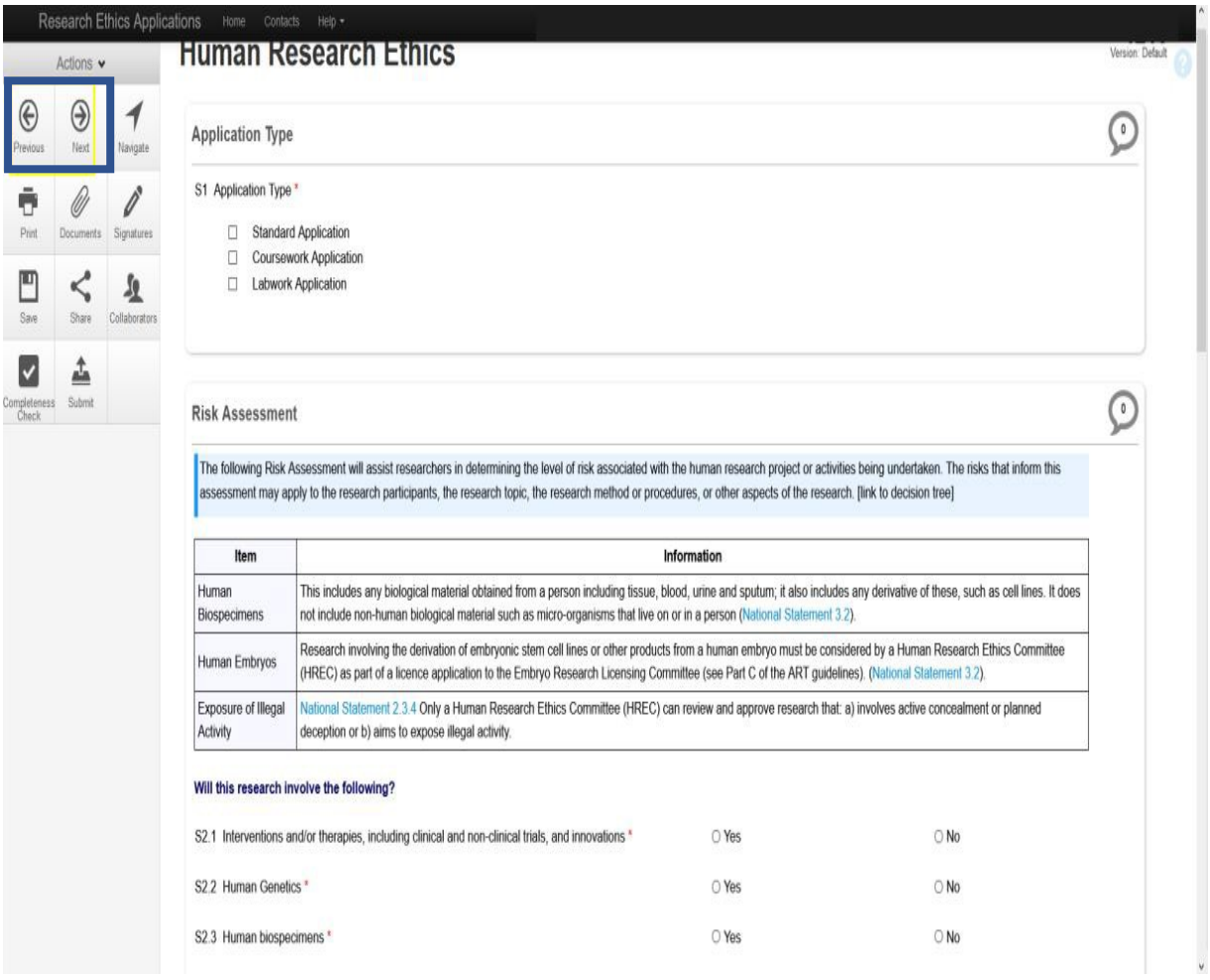
Directions for completing the Project Application are imbedded in the application. This guide is designed to sit alongside REP as you familiarise yourself with the ethics process here at RMIT. More detailed REP instructions are also available in the help section of REP along with other guidance notes on other types of applications including registration of other HREC ethical

approvals, animal ethics approvals, amendments, and progress reports.

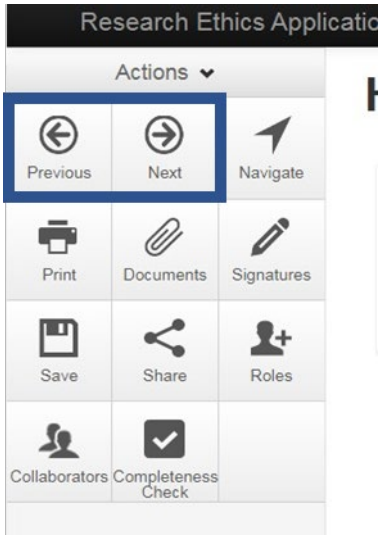
National Statement references are contained in REP and in this guide as the *National Statement* provides the foundation of the RMIT Research Policy and the RMIT Human Research Ethics Procedure. Using these references to complete your submission will hasten the approval process.

RGE Coordinators are available to assist researchers in answering questions on completing the application and about relevant guidelines. Simply email humanethics@rmit.edu.au and someone will get back to you!

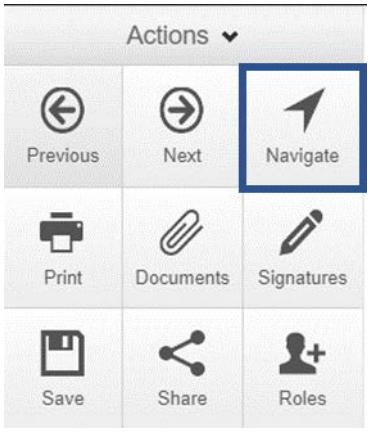
As a part of the application process, the Risk Assessment Section assists the Project Owner to identify the appropriate risk level for their project, however, at any time during the course of the review, the RMIT Ethics and Integrity Office or the RMIT HREC/CHEAN may amend the risk level and/or transfer the project to another committee at their discretion based on National Statement criteria.

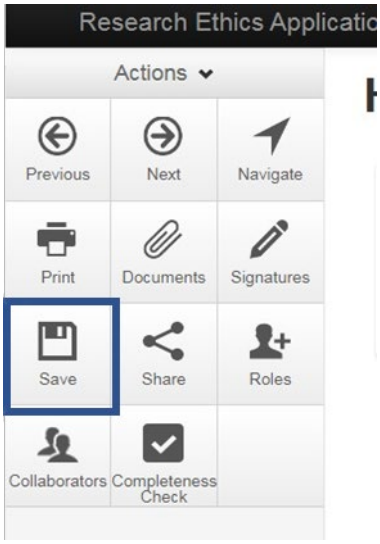


REP Application Basics:



Within the **Actions Panel** on the left hand side of the screen, use the **Previous** and **Next** buttons to move between sections within the form or use **Navigate** to return to the form overview.



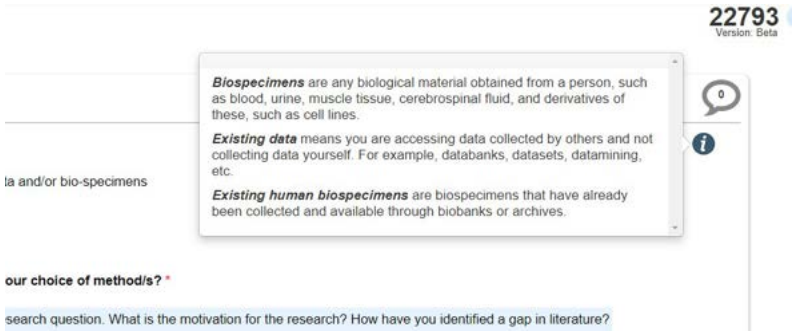


Note: After a period of inactivity, you will be logged out of the system. Please ensure you save your work regularly using the Save button on the Action Panel to avoid losing any unsaved changes.

While the system is automatically geared to save as you move between sections, it is best you save your work frequently – this will prevent any loss of data entry due to power outages, laptop battery problems, or random pets of RMIT walking across your keyboard.

Please note that all questions marked with a red asterisk (*) are mandatory and must be answered. If you think a question does not apply, write *N/A*. No response areas should be blank.

As you move through the application form, you will notice some text shaded in blue. These 'blue boxes' are tips to help you understand that specific information in regard to ethics and research is required for that question. You can also find additional guidance by clicking on the information icon within each question.



The Risk Assessment

Everything you want to consider when thinking about your human research ethics application begins with research merit and integrity, justice, beneficence, and respect. The level of potential risk to the research participant determines whether research is classified as negligible, low risk or greater than low risk research. You can read more about risk assessment in the National Statement.

This guidance will help you understand what the RMIT research governance and ethic reviewers will be looking for in your application and what you can expect in the process. We have designed this guidance to follow the format of the basic application form so let's get started!

REP will ask you questions about what you plan to do that will help you understand what level of risk your project may present – and the corresponding review pathway. You will want to have the *National Statement* with you so that you can understand some of the terminology used and the rationale for questions being asked.

The REP system builds your application based on your responses. That means that when you answer a question, the system knows whether or not to move you to the next topic or to ask you for more detail in line with the National Statement. This starts from the moment you complete the Risk Assessment. This smart system helps to eliminate questions that don't apply to your research.

Quick Tip: We won't go question by question here, lots of them are pretty straightforward. We will touch on those where people have asked us the most questions and we will identify them by the question number from REP.

Section 1: Project Summary

1.1.1 Project Title

The title should be the same as the one used on grant submissions, theses, site approvals, etc. for the same project. This may help you and RMIT offices across the university communicate if the need arises in the future. A lengthy or confusing title tends to add confusion to an application so try and keep it straightforward and based on your goals in plain language.

1.1.2 and 1.1.3 Project Aims and Rationale

What are you proposing to do? Why are you proposing to do this? What benefits do you think will come from it? How does that benefit outweigh any risk that the project activity might actually have? Have a good understanding of National Statement 1.1 through 1.13. Some of this will be addressed in other parts of the application (have a look under the **Navigate** button and you will see Sections on Participants and Consent) but those higher level portions need to be addressed here – especially consider 1.1 (a) through (d) and 1.6.

At a minimum:

- Is there a clear statement of the problem or purpose?
- Is the research question useful? Is the research worthwhile?
- Is the research likely to yield new information, enhance understanding, or clarify existing uncertainty?
- Has this, or something similar, been done in the same or similar contexts?
- Can the research proposal be supported by a systematic review of the literature that would demonstrate the importance of the research question?
- Does it build upon the results of previous research?
- Have the perspectives of potential participants groups, the wider community, or other disciplines been incorporated into the proposal where appropriate?
- Does the value of the project justify the use of human participants?

Summarise the participants and procedures involved in this research in non-technical language. This is something you are going to hear a lot! Plain language. This is really important, and you will find it referenced as 'lay language' in the National Statement at 5.2.7: *Research proposals should be clear and comprehensive, and written in lay language.*

There are reasons for this – the ethics committee that reviews your application is made up of individuals from a wide range of backgrounds – not all of them will be familiar with the particular scientific or technical words that are common to your discipline. It also helps to ensure that individuals, participants, and interested individuals will be able to understand what you are doing. The more you get used to writing for a generalised audience, the more straightforward your submission becomes and the more easily it is understood.

Quick Tip: Writing in Lay Language

Ethical review submissions including associated documents should be written in lay language (*National Statement 5.2.7*) – Think of it as writing for the average adult population. Avoid technical or professional language such as may be used in grant submissions or with peers.

Use short, clear sentences. Use bullets or timetables for multiple visits or procedures. Select an easy-to-read font size. Use second person (you) statements rather than first person. Use correct spelling and grammar. If the consent is more than one page, use footers: page 1 of 3, page 2 of 3, etc.

Within Microsoft Word you can set your Options to include the tools you need to help you determine if your submission meets these standards. The Proofing options offer lots of options to improve readability statistics as well as correcting grammar and punctuation. You can also add Grammar & Refinement settings to help you limit jargon, wordiness, and complex words.

Click on File from the top menu, then:

- Options
- Proofing
- Writing Style
- Grammar and Refinements

You will be able to select the items you want to watch for within your writing.

You will also see a tick box to show you the readability statistics.

Remember to set your spell and grammar check to “English – Australia!”

Open your document and now run the “Spelling and Grammar” or “Editor” (depending on your version of Word) check function on the Standard Toolbar .

When Microsoft Word finishes checking spelling and grammar, it will display information about the reading level of the document using the Flesch-Kincaid Reading Ease score, which rates texts on a U.S. grade-school level. This is equivalent to the Australian school levels.

To improve readability, consider using shorter words and shorter sentences.

Keeping the scientific and technical jargon to a minimum, ensuring that it is proofread, grammar and spell checked, and will significantly diminish readability issues and help you avoid rewrites later on.

1.2 Multi-institutional research

RMIT is committed to the National Statement Section 5.3 guidance on minimising the duplication of ethical review. To that end, if you are applying for a multi-institution project, consider who has overall responsibility for the project.

Are you the PI and/or is RMIT the lead institution (1.2.1.2)? You may wish to discuss this with a RGE Coordinator to determine if a full application to RMIT is necessary or if Registration of an external HREC Approval is an option for you.

1.3 Project Funding

We often get asked why we ask about research funding. National Statement 5.2.8 states *‘A researcher should disclose to the review body the amount and sources or potential sources of funding for this research.’* By doing this the HREC/CHEAN can consider the relationship between the source of the funding and the aims of the project and whether there might be any implications for the ethical conduct of the project. This is particularly important around the areas of recruitment, the information/data you are collecting, and freedom to publish.

The RMIT HREC/CHEAN are also required to ensure that there are appropriate resources available

for a project, this ensures that projects won't be abandoned and potentially leave participants in limbo or worse - harmed. Like everything else, the risk of your project is balanced against resources, an absence of funding does not equate to withholding approval – it just means the reviewers will be looking at your other risk mitigation plans. In REP the categories available include:

Category 0	Internal funding, unfunded, other.
Category 1	Australian Competitive Grants (Most typically NHMRC and ARC)
Category 2	Other Public Sector
Category 3	Industry and Other
Category 4	Cooperative Research Centre

1.4 Research Review

Has your project been reviewed elsewhere? A scientific committee? A peer review committee? If you have an outcome from that review, add that at Section 9.

1.5 Project Location

Quick Note: You might notice we skipped a number there! Remember, we aren't going to address every question – just the ones where you might have some extra questions of your own. Sometimes we might not get it right – you can always contact us and ask more questions! Contact an RGE Coordinator at humanethics@rmit.edu.au!

For RMIT campuses outside Australia, select overseas and indicate the campus at 1.5.1.1. You may be subject to human research ethics approval processes in those locations as determined by local regulations, but you will also be subject to all parameters of Australian regulations and RMIT policies.

There may be times where more than one review will be required, and you may need to do some searching to find out if countries you are working with have ethical review legislation/ regulations but knowing that will help you in your application process with RMIT. A great place to start is the International Compilation of Human Research Standards which is updated regularly by the Office of Human Research Protections in Washington DC.

1.6.2 Project Start Date

This should not be prior to ethics approval unless you have clearly articulated a research component that does not involve human participation that is a precursor to the project that is included as a foundation of the application; or you had a separate ethics approval for a prior component (such as a pilot project).

The RMIT HREC/CHEANs can only grant prospective ethical approval, never retrospective.

Section 2 Research Team

As we've already mentioned, while you may be the Project Owner and a member of the Research Team, you may not necessarily be the PI on the project. This section is where you determine where each member of the Research Team sits. You should make sure to include all investigators and those who will be involved in interacting with research participants or with handling data collected from participants.

The National Statement 1.1 requires consideration be given to the ability of a researcher to reasonably conduct or supervise the conduct of research involving human participants. To that end, the RMIT REP application asks for details in three areas on all involved investigators:

- Research activities *on this project*
- Experience and expertise *in support of their role on this project*
- Qualifications, education, or training *in support of their role on this project and specifically including research ethics and integrity undertakings.* ***Student Investigators must upload their completion certificates for the RMIT Human Research Ethics and Research***

Integrity online training modules at Section 9 of the application.

If you have a position identified, but the person has not yet been hired, describe the required qualifications or training the person will receive, as applicable. **But don't forget you will have to come back and file an amendment to add the individual if they are named after you receive ethical approval!**

Examples:

- Sam Frank and Joyce Williams, RMIT postgraduate students in Psychology, will conduct the interviews.
- An undergraduate will be hired to enter the data and will be trained in the described procedures to maintain confidentiality.
- A person certified to perform venipuncture will do the blood draws.

In the second instance, what is their experience and expertise in relation to that function you have outlined. Finally, in the third instance, what education and training have they had to support that function **and** what education and training have they undertaken in regard to the ethical conduct of human research (at a minimum, RMIT students must complete the RMIT training module).

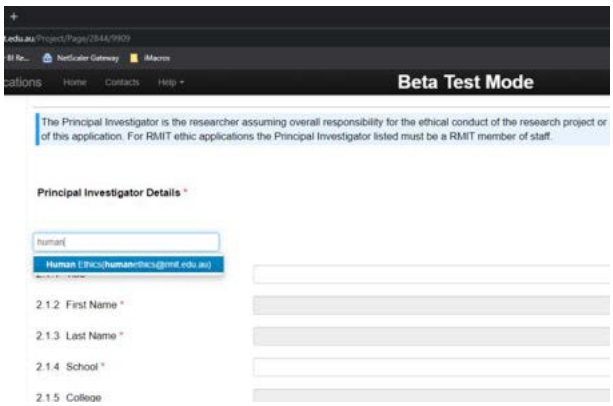
2.1 Principal Investigator

The Principal Investigator on an RMIT project application may be:

- The primary investigator on an RMIT project.
- The primary RMIT investigator on a multi-centre application where an external investigator has an overarching primary responsibility.
- The Chief Investigator on a multi-centre application where they are also the RMIT PI.
- The primary supervisor of a student who is conducting a project involving human research.

Primary supervisors must be listed as the principal investigator for all student projects with human participants. Primary supervisors are responsible for ensuring student research is conducted in accordance with RMIT policies and national guidelines, including obtaining relevant approvals. Prior to submission of a student project to the RMIT HREC, the Primary supervisor should review and approve the project in REP and any necessary Participant Information and Consent Forms. The completed project cannot be submitted in REP without the Primary supervisor's electronic signature acknowledging their acceptance of these responsibilities.

To add the PI, begin by typing their first name, last name, or staff identifier in the 'Search User' text box.

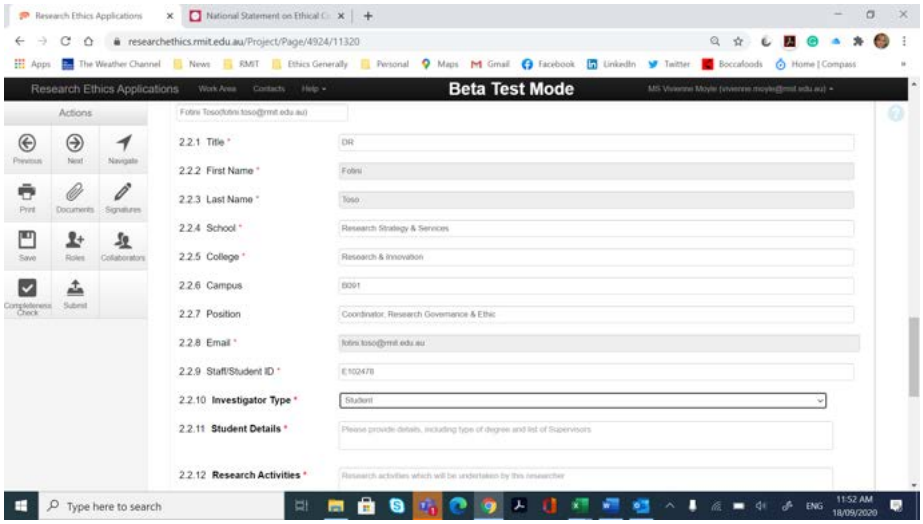


A list of matching personnel will be displayed. Click the correct person to pre-populate the form with their details.

If you unable to find an RMIT staff member or student using the search function, this probably means that they have not yet logged into the system. They will need to log in to REP to activate their access. You will need to wait for their details to be updated in the system overnight before they can be added to the form.

2.2 Other Investigators

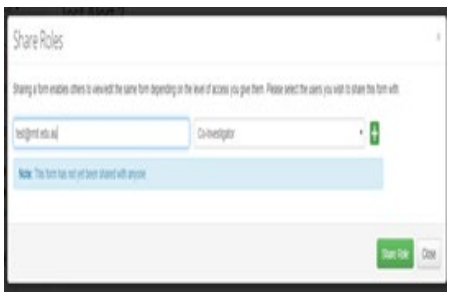
This category includes collaborators within and across schools, departments, and colleges and / or students. Their roles may be titled co-investigator, partner investigator or student investigator. It is strongly recommended that you share your application with anyone you list here as they may help strengthen it, or they may add their own details and save you some extra work.

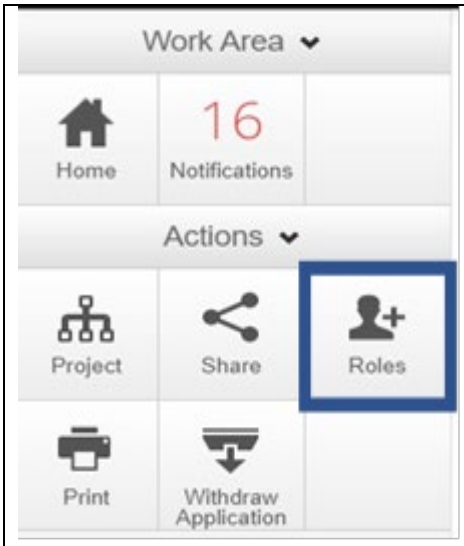


Where asked to provide other RMIT investigators, multiple researcher details can be added to the form by clicking the '**Add Another**' button located below the question.

Quick Tip: Granting Access to Co-Investigators

The Project Owner or PI can share the project with co-investigators allowing them to read, write and submit the application form as well as create and submit progress reports, amendment requests and adverse events

	To share, firstly open your project from your project list. Click the **Roles** button on the **Actions panel**. Enter the RMIT email address of the collaborator you would like to share with and select 'co-investigator' from the list of roles. Click	

	**Share Role** when done.	

2.3 External Investigators

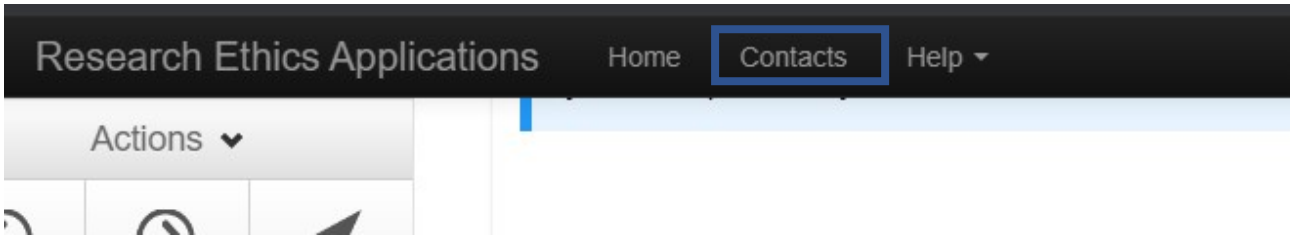
The final role is external investigator. Here you may list individuals from other universities, research institutions or industry that collaborates in the project. They will not have access to the application in REP although you will be able to provide them a PDF version of the application.

You will be required to manually enter any external co-investigators into the system. Once you have entered their details you can save them as a contact, by clicking on **Add to Contacts**.

If you collaborate with them on future ethics applications, you can choose them from your Contacts list without having to enter their details again.

This is done by clicking on the **Load** button within the question and selecting from your list of saved contacts.

Quick Tip: You can manage your list of contacts by clicking the Contacts menu item at the top of the screen



You can add, edit, and delete contacts for future use within this page.

Section 3: Research Methodology

3.1.1 Human research includes active participation, as well as non-active participation through the use of data about humans and human biospecimens.

How you respond to the initial questions in this section will determine the subsequent questions. You need to answer in line with your planned activities – if you find yourself heading in another direction you will have to file an amendment before you can do anything and that could delay your research. If you proceed without the appropriate approval you could find yourself in violation of the Australian Code for the Responsible Conduct of Research.

3.1.2 and 3.1.3 Research Methods

The National Statement gives you specific guidance on:

- Human biospecimens in laboratory based research (Chapter 3.2)
- Genomic research (Chapter 3.3)
- Animal-to-human xenotransplantation (Chapter 3.4)

The NHMRC Indigenous guideline provides specific guidance on Indigenous research methods and ethics through:

- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018
- Keeping research on track II 2018

Additional information for clinical trials can be found in the Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice, which is accepted as the standard along with the National Statement by the Therapeutic Goods Administration here in Australia.

Within REP you will see we have outlined a number of different research methods – check out the *i* box for more information on each of them. You are going to want to be able to explain why you are using these methods very clearly. Some aspects cross over but some are unique. Some are specific to RMIT. Tick all that apply.

Things to include in your methodology:

- A clear description of all aspects of the research methodology
- Justification of the methodology as appropriate to achieve the aims of your project
- An outline of the proposed method, including:
    - Data collection techniques
    - Participant task details
    - Time commitments
    - Data analysis plan
    - Description of procedures and techniques involved as appropriate and whether they are established/accepted standards

There may some very specific concerns in our research, some of these are addressed below:

- **Separating the research activity from a simultaneous treatment activity**: Where a person is involved in a physical therapy program for treatment of an injury, a researcher wants to test the reliability of various pain measures by asking the person to evaluate his pain using these instruments. In the protocol and consent, clearly indicate that the only experimental portions to be considered are related to testing the pain measures, not the physical therapy procedures.
- **Participant review/editing of contributions**: Can participants review/edit their responses or contributions prior to data analysis or publication? How and at what stage? Do you anticipate that any ethical issues may arise from accessing their responses/contributions? Describe what issues might come up and how you will manage them. This might include participants disagreeing with how their information is portrayed or the result of the analysis. If they seek to withdraw their analysis, how will this impact your research?
- **Accessing existing data or specimens from biobanks or databanks**. What types of permissions do you need? Who are the data custodians? Are the legal implications? Is the data publicly available and is it available for public use (they may be two different things)? Make sure you attach your data access terms and conditions and permits where applicable.
- **Participants and non-participants**: In certain types of research, you may have to distinguish between participants and non-participants – how do you manage that distinction? How will you accommodate those that don't want to participate?

The Office of Research Ethics & Integrity has a catalogue of resources available for you:

- Online surveys on sensitive topics with non-identifiable ('anonymous') populations FAQs
- Creative practice frequently asked questions
- Ethical issues associated with web-based surveys
- Guidance note on human research conducted in other countries
- Clinical research at RMIT
- Guidance note on human research ethics applications for Honours supervisors and students
- Research involving illegal activities guidelines

We are always looking to add more guidance notes to help, check in the help section of REP to see what's available. If you can't find what you're looking for – contact the RGE Coordinators at humanethics@rmit.edu.au and someone will help you out!

Section 4: Participant Numbers

4.1.1 Participant Population

What is the total participant population? How many individuals are you hoping to enrol? This includes at all sites if you are doing a multisite project. This also includes the total number of individuals if you plan on using groups although you will be asked for information by group a little bit later on. Take this question at face value. Total number. You will also need to explain why your proposed sample size is suitable to meet your project's goals.

4.1.2 Inclusion and exclusion criteria

What are the specific things that make someone eligible to be in your research and what will definitely keep them out? An easy example of an exclusion criteria is often something like anyone under the age of 18. An easy example of an inclusion criteria is anyone who is fluent in English.

4.1.3 Participant Groups

Are you using groups in your research? This could include focus groups when you are doing market or social research, or control and experimental groups, interview groups, a pilot study. The difference is that the data collected is group data and viewed as such. Not as individuals. If you are comparing group data – how many groups? If you have a control group and several variable groups – that would be one control group plus X variable groups. Questions 4.1.4 through 4.1.6 ask for more detail about each group but they are pretty straight forward.

4.1.7 Group Confidentiality

This is going to be different than just keeping your data confidential. You will need to consider how you will manage each group and plan for confidentiality within the group – will you discuss the concept? Will you ask them to sign a confidentiality statement?

4.1.8 Indigenous research

At RMIT we recognise and respect the unique culture and contribution that Aboriginal and Torres Strait Islander people bring to our communities. We are also proud to provide study, cultural, & personal support to our Aboriginal & Torres Strait Islander students in their learning journey.

REP guides you through a considered approach to Indigenous research to ensure the research journey continues with the same level of respect.

Remember to consider your available resources:

- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018
- Keeping research on track II 2018
- National Statement Chapter 4.7

4.1.10 Targeted populations requiring specific considerations

The National Statement Section 4 discusses the need to institute additional precautions to protect individuals that may require special considerations as research participants. This might include individuals who may have a diminished capacity to make informed decisions regarding their participation or may be susceptible to coercion due to their circumstances (e.g., inpatient) or to their relationship to the investigator. Identify any circumstances or situations where you might consider additional safeguards that may be necessary when recruiting, obtaining informed consent, or conducting other study procedures.

The list at 4.1.10 sets out a number of National Statement and RMIT identified populations that may require special consideration when conducting your research. Depending on which boxes you select, questions will come up for you to respond to which will help us better understand your planned research and the benefits and risks it may bring.
Please be sure to consider each one carefully and, as always, contact an RGE Coordinator at humanethics@rmit.edu.au if you have any questions!

Section 5: Consent

'The guiding principle for researchers is that a person's decision to participate in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.' National Statement Section 2.2.1

5.1 Recruitment

Consent starts all the way back at recruitment. How you recruit your participants has to be completely free from any coercion or even the perception of coercion.

Recruitment takes a few steps:
- identification of potential participants;
- the initial contact;
- potential screening for the inclusion and exclusion criteria you listed back in Section 4; and
- the information you share during recruitment.

Populations should not be singled out solely because they may be "easier" to recruit (for example, institutionalised persons), if the PI intends to generalise results to a wider population. If certain people are targeted for participation, state why. If groups are excluded, state why. For example, Only women will be surveyed because we want to learn how women perceive the barriers to advancement in this male-dominated field.

Care must be taken to prevent even the appearance of coercion in recruiting. Coercion is a factor if the participant perceives that they may suffer negative consequences for not participating. For example, an individual may feel they must participate if the researcher is in an authority position, such as teacher/student, care provider/patient, employer/employee, etc. relationships.

The application asks a number of questions around recruitment to make sure your project recruitment is equitable, done without coercion, and is done ethically and legally.

5.2 Informed Consent

Obtaining consent is a process, not merely having the person read a statement and sign it. The purpose is to ensure that the potential participant has complete understanding of the study and their role in it before agreeing to participate. It is the responsibility of the PI to ensure that the information is presented in a manner that each person can comprehend, that the person understands the risks and benefits, and can ask questions. The PI must also make it completely clear that the potential participant is free to either participate or not without any negative consequences and may quit at any time.

For populations that include children and or those who may be decisionally impaired, the PI must describe the conditions and procedures for obtaining appropriate consent. In some cases, (e.g., the mentally ill or aged), a determination must be made whether the person is capable or not. The procedures for this determination must be described. If it is determined that a parent, guardian, or other advocate must provide written consent, describe how this will be obtained. The participant may also be asked to provide consent/assent, if able, in addition to other consents. If this is not possible, explain why.

The consent process and the Participant Information and Consent Forms (PICF) are critically important for the protection of participants in research. Obviously, the risk involved for the

participant will determine the appropriate consent process.

The PI must obtain consent under circumstances that provide the potential participant or representative enough opportunity to consider participation and minimise the possibility of coercion or undue influence.

The information must be written in language that the person, or representative, can easily understand.

The consent must not include any language that waives or appears to waive any legal rights of the participant.

The consent must not include any language that releases the PI, RMIT, a sponsoring agency, or individuals from liability for negligence.

To ensure that participants understand the nature of the research and their personal involvement, the investigators must provide a thorough oral explanation to prospective participants and answer their questions and, unless otherwise approved by the HREC/CHEAN, obtain a signed consent from participants.

In certain circumstances, such as online surveys, a Participant Information Sheet may serve as the standalone mechanism for explanation and the survey completion will serve as implied consent.

The nature of your research and the level of risk determine the type and amount of information that you need to include. Consider what the person will need to know in order to make an informed decision to participate. For example, interviews or questionnaires with highly sensitive questions require detailed information about procedures to protect confidentiality. Research involving therapy or exercise may need more information about physical risks.

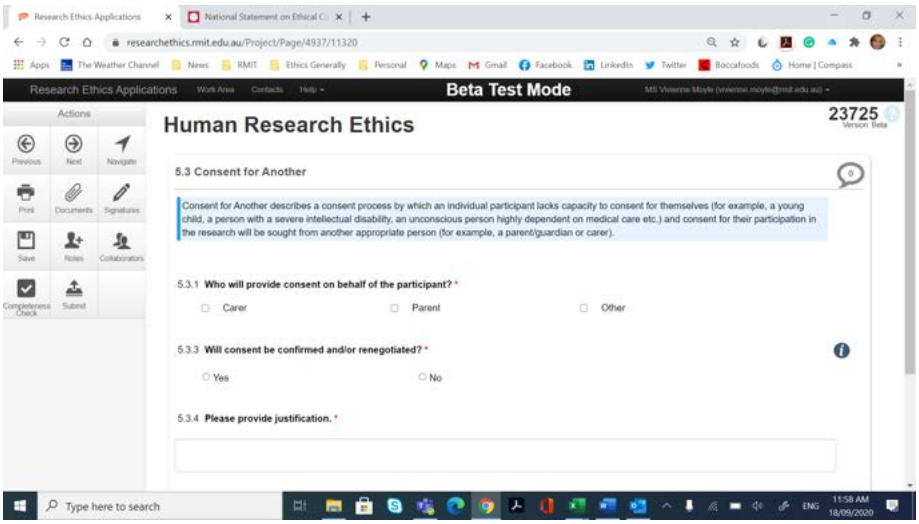
Translations of consent information are necessary for non-English speaking people. Describe how information will be translated and by whom. For greater than low risk applications, the translation must be certified and done by a qualified translator. For low and negligible risk applications, the translation may be done by native speakers or qualified educators. The PI should provide details on how the translations was obtained.

An approved RMIT Participant Information and Consent Form is available and its use is encouraged. There is a Model Information and Consent Form available for use in art, design, and creative disciplines.

For additional help in considering recruitment and consent see the following:

- Understanding consent in research involving children: The ethical issues
- Payment of participants in research

5.3 Consent for another



For a decisionally impaired person, a legally authorised representative (LAR) must provide written permission. Provide signature and date spaces for the LAR and the participant, if the latter is capable of consent.

State whether the participants and data are anonymous or confidential. If participants are anonymous, no one, including the researcher, knows the identity of those who participated in the study or which data they provided. If the information is confidential, the identity of participants and the data is known, but is kept in strict confidence within legal limits. Coding identities and storing data in locked files are methods of preventing private information about participants from being revealed.

A copy of the consent must be given to every participant. The PI retains the original signed statement. The investigator must retain these documents for at least three years past the completion of the research activity.

5.4 Opt-out consent

An 'opt-out' approach is used when it is not feasible to contact some or even all of the participants in a project. Typically, this is used when the scale of project is so large that consent would be a huge undertaking or that the project is using data previously consented and the re-consent process would be onerous. The significance of the benefit then would have a direct impact on the approvability of opt-out consent. National Statement 2.3.5 through 2.3.8 will give you more detail on this.

5.5 Limited Disclosure

Limited disclosure to participants about the aims or the methods of you're a project is sometimes used when the research goal simply could not be achieved if the information were fully disclosed. Disclosure, however, covers a spectrum and where a project sits on that spectrum plays a part in consent and ethical review. National Statement Chapter 2.3 provides information on qualifying or waiving conditions for consent with key requirements listed at 2.3.1 through 2.3.4.

5.6 Waiver of Consent

A request for a waiver of consent may be submitted when explicit consent and opt-out consent are not appropriate for the project. This means that ultimately the research participants will likely not know that they (or their tissue or data/information) has been involved in research. It should be noted that only an HREC may grant a waiver of consent for research using personal information in medical research or personal health information and in projects that may expose illegal activities. For more information and to see if your project fits into the requirements see National Statement 2.3.9 through 2.3.11.

You may have additional consent questions based on the different sections you checked earlier on in the application work through each one of them carefully and remember to contact an RGE Coordinator at humanethics@rmit.edu.au if you have any questions!

Section 6: Risk and Benefits

'Research is ethically acceptable only when its potential benefits justify any risks involved in the research.' National Statement Section 2.1

6.1.1 and 6.1.2 Risks and Risk Mitigation/Management

Study risks are not limited to physical or psychological harm. Consider any possible negative consequences to the individual for participating in your research including social, economic, and legal harm. When identifying the risks, consider the magnitude of the risk as well as the likelihood that it may occur.

Risks also apply to the research team – is there risk involved during the course of the project? Will you be in an unfamiliar location? Will you need support? If the researcher is a student, what provisions have been made by the supervisor to be maintain a level of connectivity to ensure the student's safety? What about the reputational risk to the university?

Provide information from published literature when possible and appropriate. State the precautions that you will take to minimize the risk, and procedures that you will follow if harm occurs.

For example:

- In similar studies, a few participants have become mildly upset during the interview when discussing the trauma, they witnessed. The interviewer is experienced in counselling trauma victims and will stop the interview and provide immediate support. If the anxiety persists, the following actions will be taken….
- There is a very small possibility of heart attack during the strenuous exercise in this program. However, it is very unlikely because the participants are healthy, athletic and <35 years old. Monitoring procedures conducted throughout the exercise include….
- In case of emergency, these personnel and equipment are available…. and these procedures will be followed….

Assessment and management of risk can be found in National Statement 2.1.

6.2.1 Benefits

Benefits to the individual or to society should be reasonable in proportion to the risk. A benefit is a positive outcome that a participant can reasonably expect from his/her involvement in the research procedures. Payment for participation is not considered a benefit.

6.3.1 Overall Justification

Research is ethically acceptable only when its potential benefits justify any risks involved in the research. This is your opportunity to state how the potential benefits of your project justify the risks that may exist in your research – this is where you really want to think about those core values of merit and integrity, respect, justice and beneficence. Review National Statement 2.1.

Section 7: Data Management and Privacy

7.1 Data Direct from Participants

The blue box details types of information covered under privacy protection considerations in human research. How does the information you are collecting for your project align with those details?

Depending upon the nature of the information the researcher collects; loss of confidentiality can be a serious research risk for the participant. The level of risk assumed by the participant if the information were to be known by others determines the level of safeguards that the PI should institute to protect the participants. For example:

Important things to consider here include:

- Who will (and who will not) have access to the data/information collected during the project?
- Are the storage and security measures adequate and compliant with RMIT policy?
- Are the participants clearly informed that their information will only be used for this project? Of have you clearly requested extended consent? Extended consent may remove barriers in the future if you believe you may build upon this research. An example of PICF language may include: *Be aware that in participating in this research, your de-identified data may be used to inform future research…'*

A survey or interview about individuals' illegal activities or their opinion of their job/employer has more potential for negative consequences for the participant if the information became known than a survey or interview on frequency of exercise or study habits.

What measures do you propose to protect the confidentiality of information in the course of your project? Are these adequate to give the degree of protection promised to participants? Consider using the least identification possible starting with anonymity, then coding, and eliminating collection

of unnecessary demographics and data. Destroy identifiable data or links to identifiers as soon as possible. Limit the number of people with access to identifiable, confidential data.

Video and audio recordings are considered identifiable information. The limits of their use must be clear. If information is sensitive, transcription/analysis should be completed, and the recordings destroyed as soon as feasible. If they are to be retained, state why.

7.4 Research Data Management Plan

RMIT Student and Staff Research Data Management Plan templates are available for use but you should consult with your School or College for appropriate management.

Section 8: Disclosures

The RMIT Conflicts of Interest policy applies in research as it does elsewhere, it is also addressed in the National Statement and the Code. Any conflicts should be outlined at 8.1.1.1 and appropriate mitigation plans uploaded as supporting documentation.

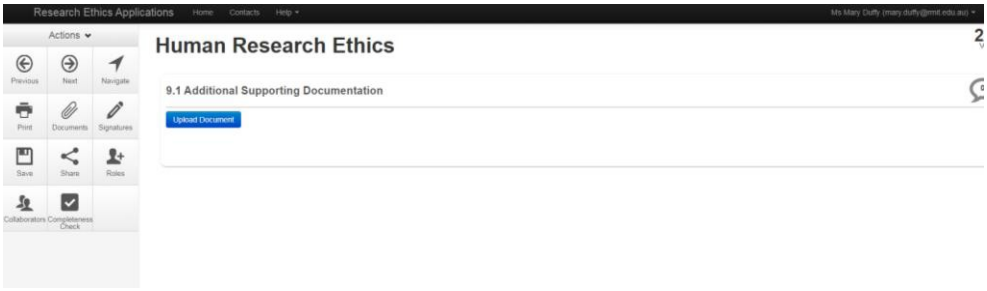
We don't often hear about restrictions placed on dissemination of research outcomes but there are occasionally some. Sometimes sponsors have restrictions on placed for timing issues or commercial in confidence items. Additionally, the Department of Defence places a restriction that anything Defence related must have one star (or equivalent) approval before publication – that includes student thesis or dissertations. These types of items should be highlighted at Section 8.2.1.1.

If you remember back Section 1.4 you were asked about other reviews? Section 8.3 specifically asks about prior ethics review. This may apply in cases where the single ethical review as not possible, perhaps in the case of international research or there was a difference in a project parameter between sites. Section 8.3.1.1 gives you the space to provide details to provide the information on prior reviews that may support a positive review from the RMIT HREC or CHEAN.

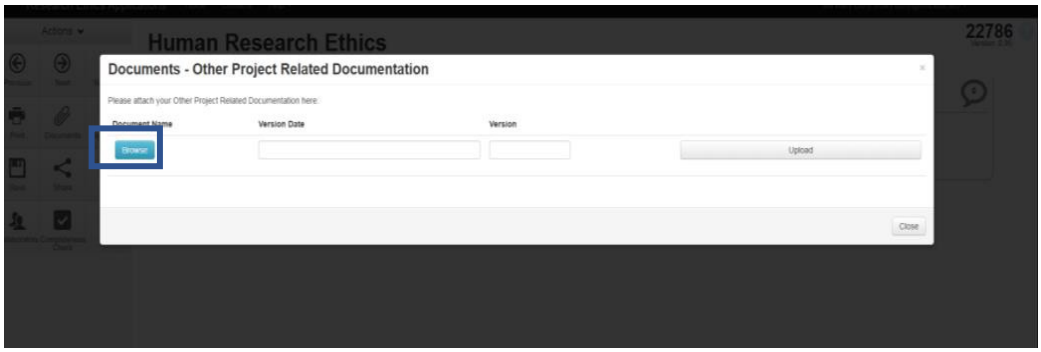
Section 9: Supporting Documentation and Declaration

You will be prompted to upload any supporting documents such as your PICF, student RMIT training completions, recruitment materials including email invitations/flyers/advertisements, research instruments (interview/focus group guides, questionnaires, etc.) as you navigate through the form.

To upload a document from your device, click on the blue 'Upload Document' button.



Click the **Browse** button to locate the relevant file. Assign a version date and number for each document you upload and use consistent file naming conventions. And then click **Upload**.

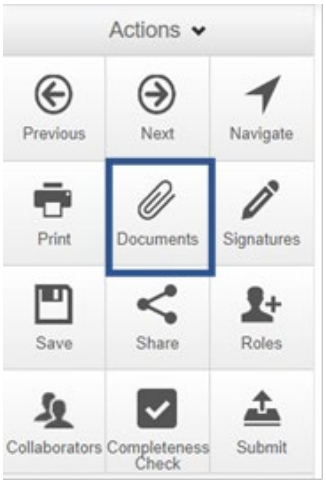


Some questions allow for multiple documents to be uploaded. If this is the case, repeat this process.

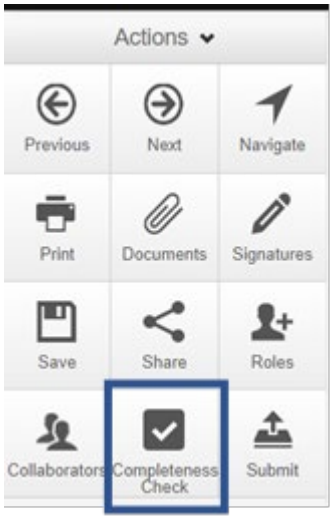
Any other documents relevant to the application can be uploaded in the 'Additional Supporting Documentation' section.

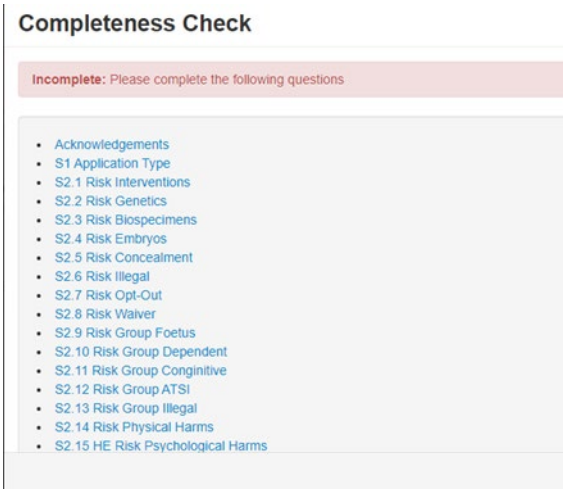
Documents must be in MS Word format only.
Please do not upload pdf copies.

You can view a list of all documents associated with the form by clicking on the **Documents** button on the **Actions panel**.



Validating the Form

When you have answered all required questions and uploaded all required supporting documents, you need to click the **Completeness Check** button in the **Actions panel**.	

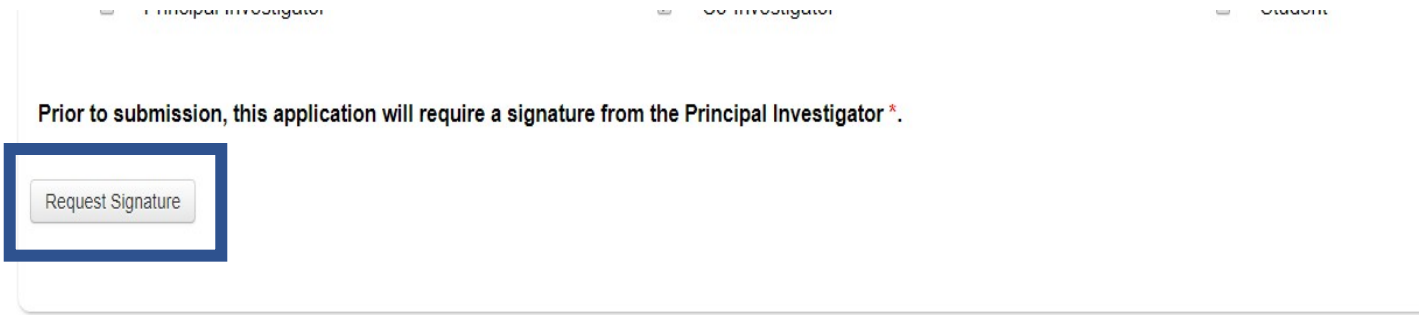
	The system will check that all mandatory questions have been addressed. A list of mandatory questions which have not been addressed will be displayed. Clicking the question within the dialog box will bring you to the relevant question within the form.

Submitting the Form

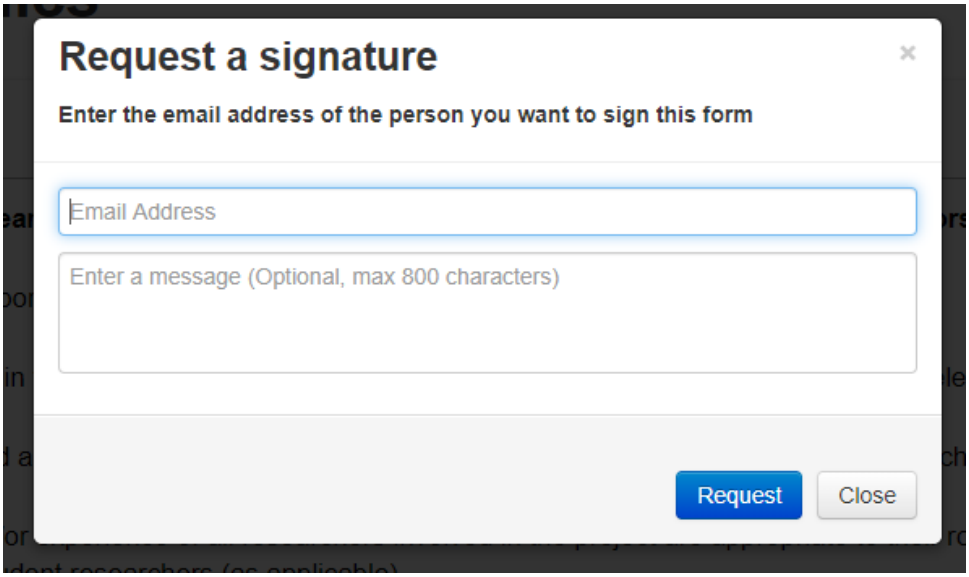
Obtaining Form Signatures

If you are submitting the form as either a co-investigator or student on a project, you will be required to obtain the signature of the PI.

To obtain a signature, click on the 'Request Signature' button

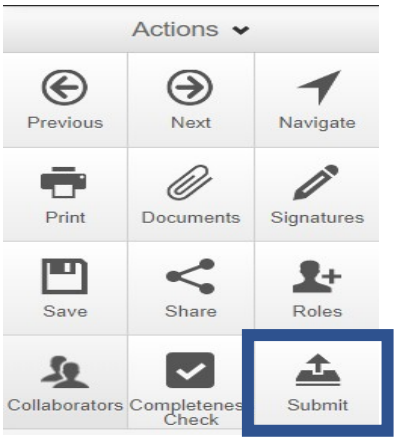


Enter the email address of the PI and an optional message in the text boxes within the dialog box and click **Request**.



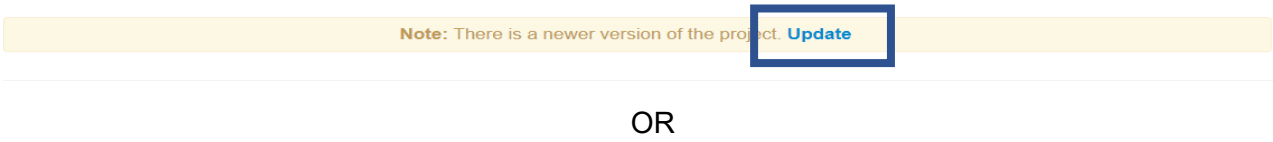
The PI will be notified of the request, and once signed you will be notified via email that the form has been signed and is ready for submission.

Form Submission



Once all mandatory questions have been completed, the application can be submitted for review by clicking the **Submit** button in the **Action panel**. Then click **Submit** again in the subsequent pop-up screen to confirm.

Quick Tip: Form Updates



OR

REP forms are updated occasionally with changes to content and/or questions. If you have not submitted your application or the form has been unlocked for amendment you may be required to update the form before you submit.

You will receive the message above at the top of your project or form if it has been updated.

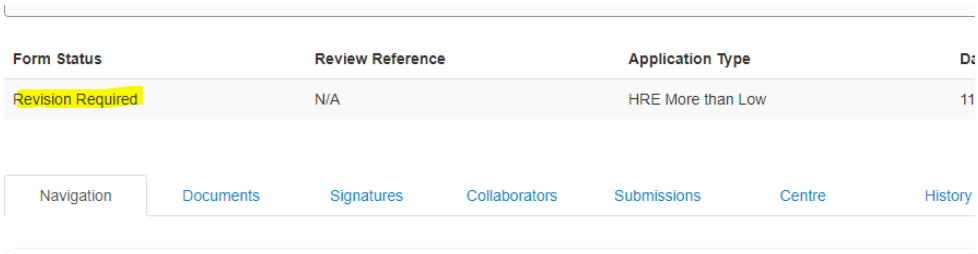
Please ensure you have saved the form and click the ‘Update’ link.

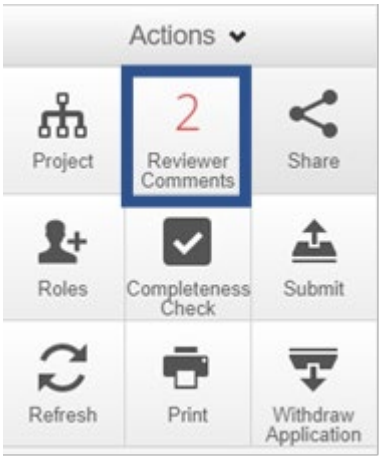
What Happens Next?

Governance Review

Within three business days of submitting a completed Ethics Application (Standard, Coursework or Labwork) on REP, an RGE Coordinator will begin a Research Governance Review.

Once your form has undergone a governance review to ensure that it is complete, you may be notified via email that further information is needed or some changes are required. The form is unlocked for you to make revisions and the status of the form updated to ‘Revision Required’.

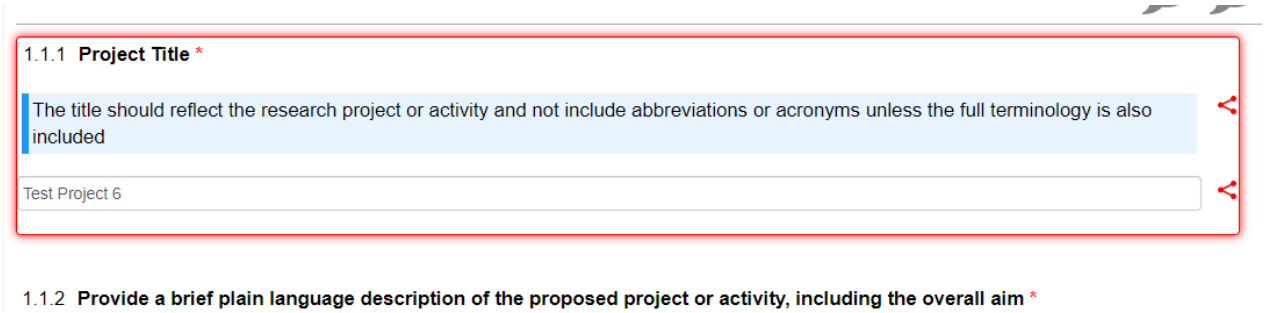




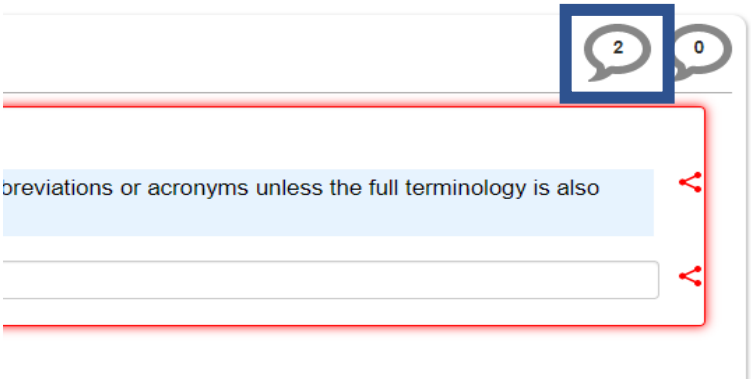
To view the comments made during governance review, click the **Review Comments** button on the **Actions panel**.

This will display a list of comments made against the current submission of the form. Click each comment to be taken to the corresponding question.

The question requiring clarification/amendment will be highlighted in red.



You can also view the comments by clicking the speech bubble above the question



Any required changes to supporting documents (PICF, recruitment material etc.) should be made using track changes and uploaded to the relevant sections of the form, with a new date and version control number. **Do not delete previous versions!**

Once you have addressed the reviewer comments, resubmit the form.

If you do not respond to the governance review within 60 days, the RGE will provide a ten (10) day reminder before withdrawing the application.

Once any necessary revisions have been made or additional information provided and the RGE Coordinator is satisfied with the application, it will be forwarded for ethical review.

Ethical Review

Once your application has been validated through the Governance Review process it will be forwarded to the relevant RMIT ethical review body based on risk level and, where applicable, College. You will be able to track your application in REP to see when it has gone for ethical review – whether it has been sent to reviewers for an out of session review or if it has been scheduled for an in session meeting. If you do have questions, you can always reach out to humanethics@rmit.edu.au.

The ethical review actions can be one of the following:

- approve the proposal as written;
- approved pending modifications;
- modifications and resubmission requested; or
- not approved; resubmission not requested.

The HREC/CHEAN actions will be communicated to the PI within one week of the completed review with instructions for any required next steps. This may include updating your online application and providing additional or amended documentation if requested by the Committee.